IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

LULA TRASS,	)	
	)	
Plaintiff,	)	
v.	)	
	)	**Civil Action No. 2:07-cv-2428 SHM/tmp**
SMITHKLINE BEECHAM CORPORATION	)	
d/b/a GLAXOSMITHKLINE, INC.	)	
	)	
Defendant.	)	

AMENDED COMPLAINT

COMES NOW Plaintiff, Lula Trass, by and through her counsel, Glenwood P. Roane, Sr., and respectfully files this Amended Complaint against Defendants, SmithKline Beecham Corporation d/b/a GlaxoSmithKline, asserting her complaint for relief of physical and mental damages caused by Defendant's product and brings this action against Defendants.

PARTIES

1.

Pursuant to Rule 21 of the Federal Rules of Civil Procedure and an agreed Order has been entered by this Court on November 14, 2007, wherein the parties agreed that SmithKline Beecham Corporation d/b/a GlaxoSmithKline is the proper Defendant in this action based on the allegations of Plaintiff's Complaint. SmithKline Beecham Corporation d/b/a GlaxoSmithKline is a corporation organized under the laws of the United States with its principal place of business located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham Corporation d/b/a GlaxoSmithKline is the sole named Defendant. Defendant's counsel will accept service of said Amended Complaint and will not contest the sufficiency of service or the jurisdiction of this

Court, or the MDL Court, over the substituted Defendant, SmithKline Beecham Corporation d/b/a GlaxoSmithKline.

2.

Plaintiff is a citizen of Arkansas.

JURISDICTION AND VENUE

3.

This Honorable Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332, as the amount in controversy exceeds $75,000 exclusive of interest and costs and because this action is brought by an individual who is a citizen of Arkansas, and the Defendant's principal place of business is located in Pennsylvania, a state other than the Plaintiff's.

4.

Venue is proper in this district pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this district. The drugs AvandiaO (Rosiglitazone), AvandametO and AvandarylCR) at issue in this suit were manufactured in this district by the Defendants at their manufacturing facility in Memphis, Tennessee. In addition, the Defendants have marketed, advertised, promoted, sold and/or distributed drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® in this district, deriving substantial compensation and revenues from those activities and made material omissions and misrepresentations and breaches of warranties in this district.

FACTUAL ALLEGATIONS

Avandia® was approved by the Food and Drug Administration ("FDA") in 1999 as an oral antidiabetic agent that acts primarily by increasing insulin sensitivity. Avandia® is recommended and prescribed for the management of Type II diabetes mellitus, also know as non-insulin-dependent diabetes mellitus ("NIDDM") or adult-onset diabetes.

5.

Plaintiff was diagnosed with Type II diabetes.

6.

Plaintiff was prescribed Avandia® (Rosiglitazone), Avandaznet® or Avandaryl®, a pharmaceutical product designed and manufactured by Defendant.

7.

Plaintiff suffered physical and mental damages caused by Defendant's product, including, but not limited to, the occurrence of a stroke as a result of being prescribed to take Defendant's product.

8.

An article entitled "Effect of Rosiglitazone on the Risk of Miocardial Infarction and Death from Cardiovascular Causes", authored by Steven E. Nissen, M.D. and Kathy Wolski, M.P.H., was published May 21, 2007 in the New England Journal of Medicine, disclosing the Endings of a meta-analysis study of published literature, information found in the FDA's website, and clinical-trials registry maintained by the manufacturers of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®.

The meta-analysis, based on a review of more than 40 existing clinical studies involving nearly 28,000 patients, showed that Avandia® (Rosiglitazone) significantly increases the risk of heart attacks, compared with other diabetes drugs or a placebo.

9.

Patients suffering from Type II diabetes have a 20.2 percent risk of experiencing a heart attack within seven years. But, a diabetic taking Avandia® (Rosiglitazone) has a 28.9 percent risk during that same seven-year period. Thus, the use of Avandia® (Rosiglitazone) causes an increased risk of heart attack, estimated at 43 percent when compared with other diabetes drugs

or placebos.

10.

The Defendants' own meta-analysis, submitted to the FDA in August of 2006, showed that Avandia® (Rosiglitazone) causes a 31 percent increased risk of heart attack.

11.

In response to the publication of Dr. Nissen's article, the FDA issued a safety alert for Avandia® (Rosiglitazone) and advised patients who take it to consult their doctors.

12.

Although the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® are marketed and sold to reduce diabetic patients' risk of heart attacks, they actually increase it (by 43 percent according to Dr. Nissen's reports and by 31 percent according to the Defendants' own analysis). Therefore, the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® do not produce the intended therapy, but instead increase the risk of heart attacks. The Defendants failed to disclose this information and have continued to market and sell the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®, thereby placing diabetic patients, including Plaintiff at an increased risk of heart attacks and use of Avandia® (Rosiglitazone), Avandamet® or Avandaryl® resulted in Plaintiff suffering a stroke in 2007.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

13.

The running of any statute of limitations has been tolled by reason of Defendants withholding and concealment of information known to them. Defendants, by suppressing reports, failed to undertake notification, failed to timely disclose known effects and defects, and misrepresented their products as safe for their intended use, actively concealed from Plaintiff and

their physicians the true risks associated with the use of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®.

14.

As a result of Defendants' actions, Plaintiff, and her physicians were unaware, and could not have reasonably known or learned through reasonable diligence earlier than six (6) months prior to the filing of this suit or within six (6) months after purchasing the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®: (1) that Plaintiff was exposed to the risks described above; and/or (2) that those risks were the direct and proximate result of Defendants' products, acts and omissions.

15.

Furthermore, Defendants are estopped from relying on any statutes of limitations because of their concealment of the true character, quality and nature of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® and the risks associated with their use. The Defendants were under a duty to disclose the true character, quality and nature of the defective drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® because: (1) this information was not readily available to the public in a form that the general public could understand, and the Defendants had exclusive control over it; and (2) Defendants knew that the information was not available to the Plaintiff, the Class Members or their physicians in a form that they could understand.

16.

Plaintiff had no knowledge that Defendants were engaged in the conduct described herein. As a result of the concealment by the Defendants of the increased risk of heart attack associated with Avandia® (Rosiglitazone), Avandamet® and Avandaryl®, the Plaintiff could not have discovered within six (6) months after purchasing the drugs Avandia® (Rosiglitazone),

Avandamet® and Avandaryl®, or earlier than six (6) months prior to the filing of this suit, that the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® had the potential to cause injury to her. The economics of the Defendants' actions should also be considered. Defendants had the ability to, and did spend large amounts of money marketing and promoting the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® as profitable products, notwithstanding their risks and defects. Plaintiff's physicians could not have conducted studies to independently determine the nature, extent and the identity of the risks associated with the drugs Avandia® (Rosiglitazone), Avandamet and Avandaryl®, and were forced to rely on the Defendants' representations.

17.

Plaintiff learned about the risk and problems associated with the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® in less than six (6) months before this suit was filed. Plaintiff purchased and ingested the defective drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® within six (6) months prior to the filing of this suit.

FIRST CAUSE OF ACTION: NEGLIGENCE

18.

Plaintiff re-alleges and repeats each and every allegation set forth above with the same force and effect as if copied herein.

19.

Defendants breached their duty and failed to exercise reasonable care in the design, manufacture, testing, processing, marketing, advertising, labeling, packaging, re-branding, distribution and/or sale of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® in one or more of the following non-exclusive respects:

a. Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that Defendant knew, or should have know, increased the risk of heart attacks and/or carried a risk of serious, life-threatening side effects;

b. Failure to adequately test the products prior to placing them on the market;

c. Failure to use care in designing, developing and manufacturing their products so as to avoid posing unnecessary health risks to users of such product;

d. Failure to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the drugs;

e. Failure to advise that consumption of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® could result in severe and disabling side effects, including but not limited to heart injury, heart attacks and death.

f. Failure to advise the medical and scientific communities of the potential to increase the risk for severe and disabling side effects, including but not limited to heart injury, heart attacks and death.

g. Failure to provide timely and/or adequate warnings about the increased potential health risks associated with use of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®; and

h. Any and all other acts of negligence with respect to the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® which may be shown at trial.

20.

As a direct and proximate result of Defendants' reckless and/or negligent conduct, for at least (8) eight years and continuing to a date within (6) six months prior to the filing of this suit, Plaintiff was prescribed, purchased and ingested the drugs Avandia® (Rosiglitazone), Avandamet® or Avandaryl®. Plaintiff suffered personal and bodily injury, expenses and

economic loss, because the drugs did not provide the intended therapy and actually increased their risks of heart attacks.

21.

Plaintiff requests and is entitled to a declaratory judgment finding that Defendants are liable to Plaintiff for personal and bodily injury damages they suffered as a result of Defendants' products and conduct. Plaintiff is also entitled to a judgment in their favor and against the Defendants for all other damages suffered by the, including economic damages.

SECOND CAUSE OF ACTION: STRICT LIABILITY

22.

Plaintiff re-alleges and repeats each and every allegation set forth above with the same force and effect as if copied herein.

23.

The drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®, manufactured marketed, promoted, sold and/or distributed by Defendants, are defective because of their manufacturing and warning defects described above.

24.

As a direct and proximate result of Defendants' defective manufacturing and warning of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®, for at least eight years and continuing to a date within six months prior to the filing of this suit, Plaintiff was prescribed, purchased and ingested the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®. As a result of having ingested the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®, Plaintiff suffered personal and bodily injury, expenses and economic loss, because the drugs did

not provide the intended therapy and actually increased their risk of heart injury and caused them bodily injury.

25.

Plaintiff requests and are entitled to a declaratory judgment finding that Defendants are strictly liable to Plaintiff and a judgment awarding them personal and bodily injury damages, expenses and economic loss suffered as a result of Defendants' products and conduct.

THIRD CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY

26.

Plaintiff re-alleges and repeats each and every allegation set forth above with the same force and effect as if fully copied herein.

27.

Defendant expressly warranted to Plaintiff (in the package inserts, the Physicians' Desk Reference, other marketing literature and documents provided to the FDA) that the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® were of merchantable quality, fit, safe, and otherwise not injurious to the health and well-being of the Plaintiff and capable of providing the appropriate therapy to Plaintiff.

28.

The Defendants' representations were material reasons why Plaintiff was prescribed, purchased and took the drugs Avandia® (Rosiglitazone), Avandamet® and AvandaryI®.

29.

The drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® that Plaintiff was

prescribed, purchased and took are unsafe, unmerchantable and unfit for their intended use, do not provide the represented or intended therapy, actually increase the risk of heart attack and heart injury, and have otherwise caused bodily injury, expense and economic loss to Plaintiff.

30.

The Defendants are merchants in the sale of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®, pursuant to Section 2-314 of the Uniform Commercial Code and other similar statutes in force throughout the United States and Tennessee.

Defendants breached express warranties of merchantability in their sale of the drugs Avandia® (Rosiglitazone), Avandamet ® and Avandaryl® to Plaintiff because the drugs are not fit for their intended purposes and are adulterated within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 351(a)(2)(B).

31.

As a direct and proximate cause of Defendants' breach of their express warranties, Plaintiff has suffered and will continue to suffer personal and bodily injury, expense and economic loss, having purchased and taken the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® which do not provide the intended and expected therapy, but actually increase their risk for heart attacks.

FOURTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY

32.

Plaintiff re-alleges and repeats each and every allegation set forth above with the same force and effect as if fully copied herein.

33.

Defendants are in the business of manufacturing and/or supplying and/or placing into the

stream of commerce the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® for the use by consumers such as Plaintiff.

34.

By placing the drugs Avandia® (Rosiglitazone), Avandarnet® and Avandaryl® into the stream of commerce, the Defendants impliedly warranted that the drugs Avandia®(Rosiglitazone), Avandamet® and Avandaryl® are of merchantable quality, are fit and safe for their intended use, and are fit for the particular purpose of providing appropriate therapies to the Plaintiff.

35.

The drugs Avandia© (Rosiglitazone), Avandamet® and Avandaryl® placed into the stream of commerce by the Defendants, are unmerchantable, are not fit and safe for their intended use or purpose, and actually increase the risk of heart attacks.

36.

The defects in the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® were present when they left the hands of the Defendants.

37.

Defendants breached implied warranties for the drugs AvandiaOO (Rosiglitazone), Avandamet® and Avandaryl o because the drugs are defective, unmerchantable and not fit for their intended purpose.

38.

Plaintiff was a foreseeable user of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®.

39.

As a direct and proximate result of Defendants' breach of the implied warranties, Plaintiff has suffered and will continue to suffer personal and bodily injury, expense and economic loss having purchased and taken the drugs Avandia® (Rosiglitazone), Avandamet® and AvandaryI®, which do not provide the intended therapy and actually increase the risk of heart attack.

FIFTH CAUSE OF ACTION: FRAUDULENT MISREPRESENATION

40.

Plaintiff re-alleges and repeats each and every allegation set forth above with the same force and effect as if fully copied herein.

41.

Defendants falsely and fraudulently promoted and represented to the medical community, the public in general, and the Plaintiff (in the packaging inserts, the Physicians' Desk Reference, other marketing literature and documents provided to the FDA) that the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® were safe and effective for treatment of patients who suffered from Type II diabetes.

42.

The representations made by Defendants were false.

43.

When Defendants made these false representations, they knew or should have known to be false.

44.

These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general and the medical community, and to induce health care providers to prescribe and dispense, and Plaintiff to purchase and take the drugs Avandia® (Rosiglitazone), Avandamet ® and Avandaryl® for the treatment of Type II diabetes, all of which evidences a callous, reckless and willful disregard for the health, safety and welfare of the Plaintiff.

45.

At the time said representations were made by the Defendants, Plaintiff was unaware of the falsity, thereof and reasonably believed to be true.

46.

In reliance on said representations, Plaintiff was induced to purchase and take the drugs Avandia® (Rosiglitazone), Avandamet® or Avandaryl® that were prescribed by her health care provider.

47.

As a direct and proximate result of Defendants' malicious, reckless and/or negligent conduct, Plaintiff has suffered and will continue to suffer personal and bodily injury, expense and economic loss, having purchased and taken the drugs Avandia® (Rosiglitazone), Avandamet© and Avandaryl®, which do not provide the intended therapy, but actually increase the risk of heart attack and heart injury continue to a date within six months prior to the filing of this lawsuit.

SIXTH CAUSE OF ACTION: FRAUDULENT CONCEALMENT

48.

Plaintiff realleges and repeats each and every allegation set forth above with the same force and affect as if fully copied herein.

49.

At all times during the course of dealings between Defendants and Plaintiff, Defendants misrepresented that the drugs Avandia® (Rosiglitazone), Avandamet© and Avandaryl® were safe for their intended use.

50.

Defendants knew or should have know that their representations were false, and should have been aware of problems with the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® before the information about their defects became known to the public.

51.

In representations made to Plaintiff and by withholding information, Defendants fraudulently concealed that the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® are adulterated within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 351(a)(2)(B), do not provide the intended therapy and actual increases the risk of heart attack and heart injury.

52.

Defendants were under a duty to disclose to Plaintiff and their physicians, hospitals and medical providers, the defective nature of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®.

53.

Defendants had access to material facts and information concerning the defective nature of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®, their defects and their propensity to increase the risk of heart attacks.

54.

Defendants' concealment and omissions of material facts concerning the safety of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® were made purposefully, willfully, wantonly and/or recklessly, to mislead Plaintiff, her physicians, hospitals and medical providers and to cause medical providers to prescribe, and Plaintiff to purchase and take the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®.

Defendants knew that Plaintiff and her physicians, hospitals and medical providers had not way of determining the truth behind Defendants' misrepresentations, concealment and omissions.

As a direct and proximate result of Defendants' malicious, reckless and/or negligent conduct, Plaintiff has suffered and will continue to suffer personal and bodily injury, expense and economic loss, having purchased and taken the defective drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®, which do not provide the intended therapy but actually increase the risk of heart attack and other heart injuries, such as strokes, continuing to a date within six months prior to the filing of this suit.

SEVENTH CAUSE OF ACTION: VIOLATION OF CONSUMER PROTECTION STATUTES

55.

Plaintiff re-alleges and repeats each and every allegation set forth above with the same

force and effect as if fully copied herein.

Defendants engaged in commercial conduct by selling the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®.

Defendants misrepresented and omitted material information regarding the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® by failing to disclose known and potential risks associated with their use.

Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretense, misrepresentation and/or knowing concealment, suppression or omission of material facts to induce others to rely thereon in connection with the sale, advertisement and purchase of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®, in violation of statutes enacted in the United States and Tennessee and designed to prevent such conduct. The United States and Tennessee have enacted statutes to protect consumers from deceptive, fraudulent and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl® were fit for the purpose for which they were intended, when in fact Defendants knew or should have known that they were defective and dangerous and actually increase the risk of heart attacks.

Defendants engaged in the deceptive acts and practices alleged herein for the purpose of selling the drugs Avandia0 (Rosiglitazone), Avandamet® and Avandaryl® to the public, including Plaintiff continuing to a date within (6) six months prior to the filing of this suit. As a direct and proximate result of the Defendants' violation of the various consumer protection statutes enacted in the United States and Tennessee, Plaintiff has suffered personal and bodily injury, expense and economic loss. Plaintiff is entitled to compensatory damages, equitable and

declaratory relief, return of the purchase price, disgorgement of profits, punitive damages, costs and reasonable attorneys' fees allowed by such statutes.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDREED, Plaintiff demands judgment against Defendants, jointly, severally and *in solido* as follows:

a. Equitable, injunctive and declaratory relief, including enjoining Defendants from further selling or distributing the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®;

b. A judgment awarding Plaintiff damages for physical and mental injuries, loss of enjoyment of life, increased risk of health problems, past and future income, past and future medical rehabilitation, life care expenses, and economic damages in an amount to be determined at trial;

c. Pre-judgment and post-judgment interest at the maximum rate allowable by law;

d. Payment of all the medical monitoring services required by Plaintiff;

e. All statutory damages allowed by Consumer Protection Statutes under United States and Tennessee laws;

f. Punitive damages;

g. Such other and further relief available under all applicable state and federal laws and any relief the Court deems just and appropriate;

h. Refund of all amounts paid by Plaintiff to Defendants for the purchase of the drugs

Avandia® (Rosiglitazone), Avandamet® and Avandaryl®.

i. Disgorgement of all profits earned by Defendants from the sale of the drugs Avandia® (Rosiglitazone), Avandamet® and Avandaryl®.

j. A trial by jury; and

k. All costs of these proceedings.

Respectfully submitted,

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By: /s/ Glenwood P. Roane, Sr.
Glenwood P. Roane, Sr., Esq. (BPR: 021358)

Counsel for Plaintiff

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Nashville, Tennessee 37238-3001

Counsel for Defendant

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing has been served upon the following persons by electronic means via the Court's CM/ECF system. I further certify that on this day I served Henry L. Hipkens, Esq. with a copy of the foregoing via facsimile at (615) 742-6200.

/s/ Glenwood P. Roane, Sr.